

101-121, 194-213, 264-280, 241-335, 183-343, 1-155, 88-228, 5-17, 21-30, 37-45, 152-170, 213-221, 260-268, 312-320, or a single ultimate species from one of (2-338)-343, 1-(6-342), or (2-338)-(6-342).

Paper No. 10, Page 2. While the Examiner admits that "the classifications for these various nucleic acids are overlapping," the Examiner nevertheless contends that "each represents a patentably distinct product with distinct physical and functional characteristics." *Id.* The Examiner further contends that:

the search for more than one product would be burdensome, because each is claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, and requires a search of the corresponding region of SEQ ID NO:1 as well as a 'reverse translation' search of the corresponding region of SEQ ID NO:2, such that each individual sequence requires two sequence searches which are not required for any of the other sequences.

Paper No. 10, Pages 2-3.

In order to be fully responsive, Applicants hereby elect, with traverse, the subject matter of a nucleic acid encoding residues 1-335 of SEQ ID NO:2. Applicants reserve the right to file one or more divisional applications directed to non-elected inventions should the restriction requirement be made final. Additionally, should the present restriction requirement be made final, Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Applicants respectfully traverse and request the withdrawal of the Restriction Requirement. As a threshold matter, Applicants point out that MPEP § 803 lists the criteria for a proper restriction requirement:

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 – § 806.04(i)) or distinct (MPEP § 806.05 – § 806.05(i)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that the nucleic acids listed by the Examiner represented distinct or independent inventions, restriction remains improper unless it can be shown that the search and examination of both groups would entail a "serious burden."

RECEIVED
AUG 20 2001
TECH CENTER 1600/2900

See M.P.E.P. § 803. In the present situation, no such showing has been made. Indeed, the Examiner has admitted that the classifications for the instant nucleic acids are overlapping, so that a search of one claimed nucleic acid would also provide useful information for other claimed nucleic acids. Accordingly, the search and examination of the instant nucleic acids would not entail a serious burden.

Moreover, Applicants respectfully point out that the Examiner has not disclosed any statutory or regulatory basis for requiring the election of an individual sequence within the previously elected Group I. Assuming *arguendo* that the Examiner is requiring an election of the members of the Markush-type claims, Applicants respectfully point out that MPEP § 803.02 requires that “[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits.” Applicants submit that the members of the Markush groups of the pending claims are sufficiently few in number and very closely related, as they are all nucleic acids encoding portions of the same amino acid sequence, so that a search of all of the members may be made without a serious burden, contrary to the Examiner’s position. Moreover, even assuming that examination of the entire claim would present a serious burden, MPEP § 803.02 states that “[f]ollowing election, the Markush-type claim will be examined fully as to the elected species and further to the extent necessary to determine patentability.” If no prior art is found “that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended.” *Id.* (emphasis added).

Further, Applicants point out that the Examiner has not addressed MPEP § 804.03, directed to nucleotide sequences. Pursuant to the notice *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996),

§804.03 holds that even when nucleotide sequences encoding different proteins are contained in an application, a reasonable number, normally ten sequences, will be examined in a single application. Applicants submit that the instant nucleic acids encode different fragments of the same protein, rather than different proteins as contemplated by § 803.04. “[N]ucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.” *Id.* Thus, Applicants respectfully submit that the present requirement for election is improper. However, even if the Examiner contends that the instant nucleic acids encode different proteins within the scope of §803.04, Applicants submit that a reasonable number of such nucleic acids should be examined together, and the Examiner has given no indication why at least ten sequences are unreasonable in the present case.

Accordingly, in view of the foregoing, all of the claims of previously elected Group I should be searched and examined in the present application. Applicants therefore respectfully request that the requirement for an election of a nucleic acid species within the previously elected Group I be reconsidered and withdrawn, and that the instant claims be examined in one application.

Conclusion

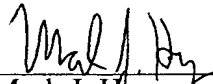
In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension

of time under 37 C.F.R. § 1.136 not accounted for in the Petition for an Extension of Time submitted concurrently herewith, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: August 15, 2001


Mark J. Hyman (Reg. No. 46,789)
Attorney for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
Telephone: (240) 314-1224

Enclosures